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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,543	09/23/2003	Michael P. Wallace	03-398 (US01)	4647
41696 7590 08/14/2007 VISTA IP LAW GROUP LLP 12930 Saratoga Avenue Suite D-2 Saratoga, CA 95070			EXAMINER YABUT, DIANE D	
			ART UNIT 3734	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/669,543

Applicant(s)

WALLACE, MICHAEL P.

Examiner

Diane Yabut

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 10, 11 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 10, 11 and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5/16/2007.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received 16 May 2007. The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 6, 8 19, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by **Engelson** (U.S. Patent No. **5,749,894**).

Claims 1-2, 8, and 19: Engelson discloses deploying a vaso-occlusive device **220** at a target site comprising one of an aneurysm **200**, a blood vessel lumen, and a fistula in a vasculature of a body and delivering energy from a source of energy located outside the body to thereby heat the vaso-occlusive device at the target site, thereby heating blood or tissue in the aneurysm (Figures 10A-12C and col. 8, lines 11-67 to col. 9, lines 1-43). Engelson discloses providing a bioactive agent carried by the vaso-occlusive device, wherein the bioactive agent is released and activated at the treatment site when the vaso-occlusive device is heated, the delivered heating energy causing a coating on the vaso-occlusive device to at least partially melt or soften, thereby releasing the bioactive agent (col. 9, lines 20-37).

Art Unit: 3734

Claims 6 and 22: Engelson discloses the source comprising a radio frequency device (col.1 , lines 4-17 and col. 6, lines 1-10).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3, 10, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Engelson** (U.S. Patent No. **5,749,894**) in view of **Yamasaki** (U.S. Pub. No. **20040215124**).

Claim 3: Engelson discloses the claimed invention except for the source comprising a magnetic resonance device.

Yamasaki teaches a method and apparatus for aneurismal treatment using a heating source comprising a magnetic resonance device (page 7, paragraph 88). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a magnetic resonance device as a source, as taught by Yamasaki, to Engelson since it was known in the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devices that absorb MRI and radiofrequency energy.

Claims 10 and 13: Engelson discloses the claimed invention including deploying a vaso-occlusive device at a target site in a body and heating a highly resistive element in

Art Unit: 3734

the vaso-occlusive device, and the vaso-occlusive device being sufficiently heated by application of magnetic field energy to at least partially melt or soften a coating on the vaso-occlusive device, thereby releasing or activating a bioactive agent carried by the device and to at least partially melt and fuse together portions thereof to stabilize the vaso-occlusive device in the three-dimensional shape (col. 9, lines 20-37), *except for* positioning the body in a magnetic resonance imaging ("MRI") device, and activating the MRI device to apply a variable magnetic field to the body.

Yamasaki teaches for positioning the body in a magnetic resonance imaging ("MRI") device, and activating the MRI device to apply a variable magnetic field to the body, which would thereby heat a highly resistive element in the vaso-occlusive device (page 7, paragraph 88). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a magnetic resonance device as a source, as taught by Yamasaki, to Engelson since it was known in the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devices that absorb MRI and radiofrequency energy.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Engelson** (U.S. Patent No. **5,749,894**) and **Yamasaki** (U.S. Pub. No. **20040215124**), as applied to Claim 3 above, and further in view of **Ken** (U.S. Patent No. **5,853,418**).

Claim 4: Engelson and Yamasaki disclose the claimed invention except for the vaso-occlusive device comprising a ferrous material.

Art Unit: 3734

Ken teaches a vaso-occlusive device comprising a ferrous material which are very sturdy alloys and tolerate significant flexing (col. 4, lines 61-67 to col. 5, lines 1-10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a ferrous material for the vaso-occlusive device, as taught by Ken, to Engelson and Yamasaki in order for the device to tolerate significant flexing.

6. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Engelson** (U.S. Patent No. **5,749,894**), as applied to Claim 19 above, and further in view of **Ken** (U.S. Patent No. **5,853,418**).

Claim 20: Engelson discloses the claimed invention except for the vaso-occlusive device comprising a ferrous material.

Ken teaches a vaso-occlusive device comprising a ferrous material which are very sturdy alloys and tolerate significant flexing (col. 4, lines 61-67 to col. 5, lines 1-10). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a ferrous material for the vaso-occlusive device, as taught by Ken, to Engelson in order for the device to tolerate significant flexing.

7. Claims 5 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Engelson** (U.S. Patent No. **5,749,894**) as applied to Claims 1 and 19 above, and further in view of **Maitland** (U.S. Patent No. **6,740,094**).

Claims 5 and 21: Engelson discloses the claimed invention except for the source comprising an ultrasound device acoustically coupled to an exterior of the body.

Art Unit: 3734

Maitland teaches a source comprising an ultrasound device acoustically coupled to an exterior of a body, which allows for both local or remote heating (col. 6, lines 26-57). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an ultrasound device source, as taught by Maitland, to Engelson in order to allow for both local or remote heating and since it was known in the art that acoustic/ultrasound waves effectively heat materials that are commonly used in vaso-occlusive devices that absorb ultrasonic energy.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Engelson** (U.S. Patent No. **5,749,894**) and **Yamasaki** (U.S. Pub. No. **20040215124**), as applied to Claim 10 above, and further in view of **Lennox** (U.S. Patent No. **5,405,322**).

Claim 11: Engelson and Yamasaki disclose the claimed invention including being heated by application of magnetic field energy, except for being sufficiently heated to cause coagulation of blood at the target site.

Lennox teaches a method for treating aneurysms using a thermal source for a body to be sufficiently heated to cause coagulation of blood at the target site in order to form fibrous scar tissue in the weakened aneurysm wall and reduces compliance and arrest aneurysm formation (col. 4, lines 13-25). It would have been obvious to one of ordinary skill in the art at the time of invention to provide heat to cause coagulation of blood at the target site, as taught by Lennox, to Engelson and Yamasaki in order to form

Art Unit: 3734

fibrous scar tissue in the weakened aneurysm wall and reduces compliance and arrest aneurysm formation.

9. Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ken** (U.S. Patent No. **5,853,418**) in view of **Yamasaki** (U.S. Pub. No. **20040215124**).

Claims 14-15: Ken discloses the claimed invention, including deploying a vaso-occlusive device **318** in an aneurysm **314**, the device including a highly conductive coil forming a lumen and formed of platinum, and a highly resistive element at least partially disposed in the lumen and comprising ferrous (containing iron) material and heating the highly resistive element, and, by way of convective heat transfer from the highly resistive element, heating the coil (Figures 11A-11D, col. 4, lines 47-67 to col. 5, lines 1-10, col. 9, lines 16-43), except for applying magnetic field energy to the device from a source located outside of the body.

Yamasaki teaches applying magnetic field energy to a device from a source located outside of the body (page 7, paragraph 88). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a magnetic resonance device as a source, as taught by Yamasaki, to Ken since it was known in the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devices that absorb MRI and radiofrequency energy.

Art Unit: 3734

10. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Ken** (U.S. Patent No. **5,853,418**) and **Yamasaki** (U.S. Pub. No. **20040215124**), as applied to Claim 14 above, and further in view of **Lennox** (U.S. Patent No. **5,405,322**).

Claim 16: Ken and Yamasaki disclose the claimed device except for the coil being sufficiently heated to cause blood coagulation in the aneurysm.

Lennox teaches a method for treating aneurysms using a thermal source for a body to be sufficiently heated to cause coagulation of blood at the target site in order to form fibrous scar tissue in the weakened aneurysm wall and reduces compliance and arrest aneurysm formation (col. 4, lines 13-25). It would have been obvious to one of ordinary skill in the art at the time of invention to provide heat to cause coagulation of blood at the target site, as taught by Lennox, to Ken and Yamasaki in order to form fibrous scar tissue in the weakened aneurysm wall and reduces compliance and arrest aneurysm formation.

11. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ken** (U.S. Patent No. **5,853,418**) and **Yamasaki** (U.S. Pub. No. **20040215124**), as applied to Claim 14, and further in view of **Engelson** (U.S. Patent No. **5,749,894**).

Claims 17-18: Ken and Yamasaki disclose the claimed device including the coil being deployed in the aneurysm in a three-dimensional shape, except for the coil being sufficiently heated to at least partially melt or soften a coating on the coil, thereby releasing or activating a bioactive agent, and at least partially melting and fusing together portions thereof to stabilize the coil in the three-dimensional shape.

Art Unit: 3734

Engelson teaches a coil being sufficiently heated to at least partially melt or soften a coating on the coil, thereby releasing or activating a bioactive agent, and at least partially melting and fusing together portions thereof to stabilize the coil in the three-dimensional shape (col. 9, lines 20-37). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Ken and Yamasaki by providing the melting of a coating on the coil to release or activate a bioactive agent, as taught by Engelson, since it was known in the art that bioactive agents may have beneficial antimicrobial, anti-cancer, or antiviral effects which are commonly released or activated by heat.

Response to Arguments

12. Applicant's arguments filed 16 May 2007 have been fully considered but they are not persuasive.

13. The applicant argues that Engelson does not teach the heating of a vaso-occlusive device using a source of energy located outside a body, but rather using a light-emitting device that "has been introduced into the region just outside the mouth of the aneurysm," and therefore is inside of a blood vessel, which is inside the body.

The examiner disagrees. Engelson does in fact teach the light-emitting device **224** in Figure 10D to be inside the body, but what is recited and necessitated is "*the source of energy [being] located outside the body,*" and Engelson discloses a light-emitting device that is inherently charged by an energy source outside the body (proximal of proximal end of catheter **204**), such as a power supply, which is especially inherent because the

Art Unit: 3734

light-emitting device is not implantable, but is removed from the blood vessel after it heats the vaso-occlusive coil.

The applicant also argues that Engelson does not disclose or teach a method of releasing or activating bioactive agents at the treatment site when the vaso-occlusive device is heated. The examiner disagrees. Engelson teaches using bioactive agents such as polysaccharides (col. 4, lines 61-67).

14. Applicant argues that there is no suggestion or motivation to modify Engelson in view of Yamasaki to use MRI energy to release or active bioactive agents at the treatment site. The examiner disagrees and recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In this case, the examiner maintains the position above that it was well known in the art that an MRI source yields higher temperature to effectively heat materials that are commonly used in vaso-occlusive devies that absorb MRI and radiofrequency energy.

15. Applicant argues that there is no mention or suggestion in Ken that such "modes amounts of iron" in the stretch-resisting filament are provided in adequate concentration to cause the stretch-resisting filament to act as a heating member. The examiner disagrees. What is recited in Claim 4 is that the vaso-occlusive device comprises a ferrous material, and Ken teaches this limitation, as mentioned above. Although the

Art Unit: 3734

claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

16. Applicant also argues that there is no suggestion or motivation to use ultrasound waves to reform the polymeric material of Engelson. The examiner disagrees. As maintained above, it was known in the art that acoustic/ultrasound waves effectively heat materials that are commonly used in vaso-occlusive devices that absorb ultrasonic energy.

17. Lastly, the applicant argues that the source of energy used in the methods of claims 11 and 16 is located outside the body, with no electrodes placed internally in the blood vessel. However, the examiner asserts that the source of energy is for the electrodes, an RF heating source, as seen in Figures 3 and 9, are outside external to the body, and therefore the method of causing blood coagulation in order to form fibrous scar tissue would have been obvious to implement in Ken and Yamasaki.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3734

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY


MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER